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10/602,859

06/25/2003

Douglas Casterlin

3081

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7590

11/03/2006

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,859

Applicant(s)

CASTERLIN ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-6 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 9/12/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2-4, 7 cancelled.
 2. Claims 1, 5-6 and 8-10 are under examination.
1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

2. Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

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The instant invention directs to a device for detection of analytes in a sample. With respect to claims 8-10, applicant recites the groove within the device has sufficient width to accommodate a plurality of test strips in contiguous without spaces between individual test strips (See Figure 19). Such modification, according to applicant's Remarks, are illustrated in Figure 19 (See Remarks, page 6, first and second paragraph). It is noted that the instant invention using test strips inserted in the groove area for testing of target analyte. The principle is based on capillary absorption and chromatographic movement (See 18, second paragraph). If under such a modification, i.e. a plurality of test strips attached together without spaces between individual strip, there would result in interference or cross-reaction between each strip due to the close range of distance between each strip. This modification eventually would confusing results for multiple analytes detection. Thus, such modified features would inevitable impose undue experimentation to one ordinary skill in the art as to how to use and detect multi-analytes in a sample.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 5-6 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 7, "opposed means" is vague and indefinite. The wording is not correct for "opposed means" because it is not proper under 35 USC 112, 6th paragraph "means-plus-function". There is no "opposed means" in the groove. Applicant needs to clarify.

Claim Rejections - 35 USC § 102

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5-6 and 11 rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US 6818452) are maintained.

Wong et al. teach a device for analyzing target molecule in a sample. The device comprises a thin flat core member having at least one groove indented into a face thereof, where an immunoassay test strip is placed in said groove (see component 441 as test strip and component 418 as groove for placing said test strip in Figure 8) and means on the opposed longitudinal side walls of grooves for retaining test strips in respective groove (See Figure 8, the bottom of the groove 418 can be means for retaining test strips).

With respect to claim 5, Wong et al. teach a pluralities of nibs (component 414, 434) projections on the grooves as means for retaining test strips in the device (Figure 8).

With respect to claim 6, Wong et al. disclose that the grooves are positioned in parallel (See Figure 8-9).

With respect to claim 11, Wong et al. teach that the device comprises a front panel for access of test strip and allow for reviewing test results (See Figure 8-9).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 5-6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cipkowski et al. (US 5976895) in view of Sun et al. (US 6372516).

The applied reference has a common inventor Cipkowsky with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Cipkowski et al. teach a device for detection of multiple analytes in a sample. The device comprises a thin flat core member having at least one groove indented into a face thereof, where an immunoassay test strip is placed in said groove (see claim 4; Figure 1 and Figure 7; Note, Cipkowski et al. use the term “slot” instead). However, Cipkowski et al. do not explicitly teach using means on opposed longitudinal side walls for retaining test strips.

Sun et al. teach a device for detection of analyte in a sample. The device also contains test strip for measuring analytes. Sun et al. teach using opposed longitudinal side wall nibs for retaining test strips (See Figure 1 component 58a and 58b).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Cipkowski et al. with the side wall nibs as taught by Sun et al. to retain test strips in the groove to further secure test strip in the groove.

With respect to claim 5, it would have been obvious to one ordinary skill in the art at the time the invention was made to have plurality of nibs projecting from opposed longitudinal side walls for holding more test strips in different grooves.

With respect to claim 6, Cipkowski et al. disclose that the grooves are positioned in parallel (See Figure 1).

With respect to claim 11, Cipkowski et al. teach that the device comprises a front panel for access of test strip and allow for reviewing test results. Surpa.

Response to Applicant's Arguments

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5. The rejections of claims 1, 3, 6, 8-9, rejected under 35 U.S.C. 102(b) as being anticipated by Willis et al. (EP 0837320) are withdrawn because Willis et al. do not teach the feature of “means on opposed longitudinal side walls of each groove for retaining test strip”.

6. The rejections of claims 1, 3-4, 6, 8-11 rejected under 35 U.S.C. 102(e) as being anticipated by Tydings et al. (US 6805838) are withdrawn because Tydings et al. lack the feature of “groove” and “means on opposed longitudinal side walls of each groove for retaining test strip”.

Wong et al. reference

Applicant argues that the recesses and the projections retaining the test strip used in Wong et al. reference do not have the structure of “means on opposed longitudinal side walls of each groove for retaining test strip”.

Applicant arguments have been considered, but are not persuasive.

As described in the specification Figure 8 and 9(Col. 8, line 24-35)—

The strip assembly 10 according to the invention may be disposed in the cassette 400 and retained by a first group of recesses 412 and projections 414..... A drug test strip 420 is also disposed in the cassette 400 and retained by a second group of recesses 432 and projections 434.

The component 414 and 432 are considered “means on opposed longitudinal side walls of each groove for retaining test strip”. The specification clearly indicates that its function is to retain test strip therein. Therefore the reference of Wong et al. anticipates the instant invention.

Conclusion

7. No claim is allowed.

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

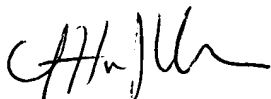
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641



October 24, 2006



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